PORT IMPORTANT RISK INFORMATION

DIGNITY® CT PORTS
Indications for Use: The Medcomp® Gen III Power Injectable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the power injectable infusion port is indicated for power injection of contrast media. For power injection of contrast media the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

Contraindications: This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. The device is also contraindicated: When the presence of device related infection, bacteremia, or septicemia is known or suspected. When the patient's body size is insufficient for the size of the implanted device. When the patient is known or is suspected to be allergic to materials contained in the device. If severe chronic obstructive lung disease exists. If the prospective insertion site has been previously irradiated. If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. If local tissue factors will prevent proper device stabilization and/or access.

DIGNITY® TITANIUM
Indications for Use: The CT Power Injectable Implantable Infusion Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition, solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the Power Injectable Implantable Infusion Port device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

Contraindications: This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. The device is also contraindicated: When the presence of device related infection, bacteremia, or septicemia is known or suspected. When the patient's body size is insufficient for the size of the implanted device. When the patient is known or is suspected to be allergic to materials contained in the device. If severe chronic obstructive lung disease exists. If the prospective insertion site has been previously irradiated. If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. If local tissue factors will prevent proper device stabilization and/or access.

PRO-FUSE® CT
Indications for Use: The Medcomp® Gen III Power Injectable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the power injectable infusion port is indicated for power injection of contrast media. For power injection of contrast media the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

Contraindications: This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. The device is also contraindicated: When the presence of device related infection, bacteremia, or septicemia is known or suspected. When the patient's body size is insufficient for the size of the implanted device. When the patient is known or is suspected to be allergic to materials contained in the device. If severe chronic obstructive lung disease exists. If the prospective insertion site has been previously irradiated. If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. If local tissue factors will prevent proper device stabilization and/or access.

Refer to Instructions for Use provided with the product for complete instructions, warnings, precautions, and contraindications. Observe all instructions for use prior to using products. Failure to do so may result in patient complications.

DIGNITY® TITANIUM

Titanium	Mini, Low Profile, Mid Sized	Polyurethane	5cc/sec @ 300psi	Attachable, Pre-Attached	5F, 6.6F, 8F
Port Material	Configurations	Catheter Materials	Injection Rating	Catheter Configurations	French Sizes

TITANIUM BODY

SCULPTED SIDES

PATIENT-CENTRIC DESIGN

	OPEN SUTURE HOLES	
DIGNITY® MINI		
5F ATTACHABLE	MRDT50ASN	5/BOX
6.6F ATTACHABLE	MRDT66ASN	5/BOX
DIGNITY® LOW PROFILE		
6.6F PRE-ATTACHED	MRDT66PLN	5/BOX
DIGNITY® MID-SIZED		
6.6F ATTACHABLE	MRDT66AMN	5/BOX
8F ATTACHABLE	MRDT80AMN	5/BOX
6.6F PRE-ATTACHED	MRDT66PMN	5/BOX

SET CONTENTS:
(1) CT Implantable Port
(1) Catheter
(1) Scalpel
(1) Introducer Needle
(1) Guidewire
(2) 10cc Syringes
(1) Peelable Introducer
(1) Tunneler*
(2) 22ga Huber Needles
(1 Straight, 1 Right Angle)
(1) Blunt Tip Needle
(1) Patient Information Pack
(1) Patient Chart Sticker

* 8F KITS have (2) Tunnelers

MR Conditional – 3 Tesla (artifacts may present imaging problems if MRI area of interest is on or near area where device is located)

Refer to the Table of Contents for Important Risk Information regarding this device.